

US EPA ARCHIVE DOCUMENT

Early Assessment for OP uses with Very Low Risk Contribution and/or High Public Value

I. Introduction

Should certain OP uses be “guaranteed” space in the risk cup if they pass a set of yet-to-be-defined criteria? This paper lays out a framework for discussion of potential criteria.

II. Should the Agency attempt/endeavor to identify OP uses with a NEGLIGIBLE CONTRIBUTION TO RISK for early retention in the risk cup? If so, how should this be accomplished, and what should the criteria be for eligibility?

“Negligible contribution to risk” could be defined using the following types of criteria:

- **Non-detectable residues at harvest and/or consumption:**
 - Are studies available that demonstrate that residues were not detected at harvest or in market basket surveys (or in other point of consumption studies)?
 - Is the use limited to all, or mostly all, processed foods and are residues very unlikely in processed foods?
 - Is the detection limit sufficiently sensitive to assure that undetected residues could not contribute significantly to risk?
 - Is the use very unlikely to lead to residues in consumed food (e.g., seed treatment)?
- S Are there data to show the use does not contribute to residues in water.
- S Have worker and ecological risks been addressed?

OR

- **Low consumption food items, especially by children:**
 - Is the OP used on a food that is a low consumption food item nationally or for certain regional population (e.g., guayanaba), based on consumption studies?
 - Is the food commodity unlikely to be eaten by children (e.g., coffee)?
 - Is the food commodity a very low portion of childrens’ diet?

OR

- **Opportunities for risk mitigation:**
 - Has dietary exposure been minimized to extremely low levels through measures (e.g., reduced application rates, increased pre-harvest treatment intervals) while

still preserving the efficacy of the OP use?

III. Should the low or negligible contributors to risk also have some demonstrated high value, such as, at a minimum, lack of available, cost-effective alternatives (see discussion in item IV below)?

IV. Further Policy Issues for the Work-Group Discussion

- **Excluding Childrens' Foods:**
 - Should the Agency not include in this category any of the top 20 food commodities eaten by children, regardless of the level of risk contribution and/or public value?
- **Including High Value to Society:**
 - Should the Agency attempt/endeavor to identify OP uses with a “very high value to society” for early retention in the risk cup?
 - Should this option for an early, “guaranteed spot” in the risk cup be available only for very low contributors to risk, regardless of level of value to society?
 - “High value to society” could be defined using the following types of criteria:
 - Value to public health program;
 - Impact on the food supply; and,
 - Importance to eradication programs.
- **Reassessing Tolerances:**
 - Can these “early assessments” be counted as reassessed tolerances?
 - Would these tolerances be viewed as “conditional”?
 - Should the dietary risks for an individual OP’s risk cup have to be balanced before an early assessment is eligible for space in the cumulative risk cup?
- **Filling the Risk Cup:**
 - How stringent should the criteria be to get an early, “guaranteed spot” in the risk cup?
 - Should there be a set proportion of the risk cup that these “early assessments” are allowed to fill (e.g., maximum of 2%, 15%, 50%) or should the proportion be dictated by some negligible risk measure (e.g., each such use would reflect a certain percentage of the risk cup, such as 0.01% or 0.1%)?